



**DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington, DC 20420**

IL 12-2003-001

In Reply Refer To: 12

February 27, 2003

RESEARCH AND DEVELOPMENT LETTER

**REQUEST FOR PROPOSALS FOR A VA-DOD COLLABORATIVE RESEARCH
PROGRAM ON IMPLANTABLE CARDIOVERTER DEFIBRILLATORS AND
ANTIARRHYTHMIA DRUGS**

1. Request for proposals for a VA-DOD collaborative research program to examine the use of implantable cardioverter defibrillators (ICDs) and antiarrhythmic drugs. Funded studies will provide greater understanding of ICDs and complementary medications, resulting in improved treatments for the veteran and civilian populations. Research proposals will be accepted from Department of Veterans Affairs (VA) investigators. Department of Defense (DOD) investigators may submit only in collaboration with a VA investigator. Results of research will be shared with DOD.

2. ICDs have significantly reduced the incidence of sudden cardiac death in patients with ischemic heart disease and reduced ventricular function. Treatment of ICD patients with antiarrhythmic drugs such as amiodarone is routine clinical practice, based on the concept that these drugs decrease the number of ICD discharges. Further studies evaluating the effectiveness of such complementary therapy are warranted, as antiarrhythmia drugs are potentially toxic. Studies which may be appropriate in response to the ICDs and antiarrhythmic drugs initiative include, but are not limited to:

a. Clinical or epidemiological approaches to evaluate the effectiveness of concomitant antiarrhythmic therapy in patients with ICDs.

b. Identification of genotypic markers to identify ICD patients who will respond to antiarrhythmic drug therapy.

c. Development of model systems to facilitate experimental studies on the effectiveness of antiarrhythmic drugs and ICDs in ventricular tachycardia.

3. Qualified independent VA investigators are invited to submit a Letter of Intent (LOI) for Merit Review proposals. VA investigators must be eligible for Medical Research Service funding before proposal submission. Investigators whose LOIs satisfy the criteria for the initiative will be invited to submit full proposals. Proposals will be reviewed by the appropriate MRS subcommittee. Proposals funded under this initiative may be held in conjunction with another VA Medical Research Service Merit Review, and are therefore excepted from the single Merit Review rule for VA investigators. Attachment A includes instructions for LOI

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preparation, general information about proposal submission, and a timetable for submission and funding. **NOTE:** *The LOI must be received no later than March 17, 2003.*

4. Duration of proposals is up to 3 years (with the possibility of 1 year of additional funding for data evaluation, to be requested during the final year of the proposed study). The total proposed budget for a non-collaborative proposal is limited to a maximum of \$450,000. Collaborative proposals, with a VA investigator as principal investigator (PI) and a DOD collaborator as Co-PI, may request a maximum of \$900,000.

5. Questions may be directed to Dennis Przywara, Ph.D. at (202) 408-3610 or e-mail dennis.przywara@hq.med.va.gov.

Nelda P. Wray, M.D., M.P.H.
Chief Research and Development Officer

Attachment

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ATTACHMENT A

FORMAT FOR PROPOSALS

1. INSTRUCTIONS FOR SUBMISSION OF LETTER OF INTENT (LOI)

The LOI is limited to three single-spaced typed pages providing an overview and description of the proposed project. Use only letter-quality print; do not use a dot matrix printer. Do not use photo reduction or small fonts.

a. **First Page.** The first page is to begin with the following information, listed in the order specified:

(1) LOI-ICD and Antiarrhythmia Drugs.

(2) Proposed project title (limited to 72 characters including spaces).

(3) Principal Investigator(s) name, degree, title, mailing address, E-mail address, telephone and FAX numbers.

(4) Name of Department of Veteran Affairs (VA) and (if appropriate) Department of Defense (DOD) research facility.

(5) Administrative contact name and telephone number.

(6) Name, title, address, and signature of Associate Chief of Staff for Research and Development (for VA) and DOD equivalent (if appropriate).

b. **Text of the LOI.** The text of the LOI is limited to two single-spaced typed pages. The text needs to follow the format and incorporate the subheadings specified in the following:

(1) **Title of Proposed Project.**

(2) **Background.** Indicate the scientific basis (rationale) for the research and its relationship to other major research findings. Describe the significance of the research.

(3) **Research Objectives.** Outline precisely and clearly the goals of the planned project, including the hypothesis to be tested and the specific objectives of the project.

(4) **Project Design and Methods.** Briefly define and describe the approach to the research.

c. **Biosketch.** Provide a brief biosketch of the principal investigator(s). Do not exceed one page per investigator.

d. **Publications.** List the most recent and/or relevant publications of the principal investigator(s). Include the full titles of the publications. Do not exceed one page per investigator.

- e. **Submission.** Submit the original plus eight copies

- (1) By mail to:

Medical Research Service (121E)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

- (2) By courier to:

Department of Veterans Affairs
Medical Research Service
1400 I Street, NW
Suite 400
Washington, DC 20420

NOTE: The telephone number for FEDEX purposes is: (202) 408-3600.

- f. **Due Date.** LOIs must be received by March 17, 2003.

2. INFORMATION FOR SUBMISSION OF PROPOSALS

a. **Merit Review Proposal Submissions.** Merit Review proposal submissions are appropriate for independent investigators. Proposals may be submitted by VA investigators and collaborating DOD investigators with approved LOIs. The proposed studies must not overlap with other, concurrently funded research studies. Proposals approved for funding under this solicitation will be considered as additions to ongoing VA Merit Review programs.

b. **Investigator.** An investigator may be PI or Co-PI on only one application submitted in response to this solicitation. Each PI or Co-PI must be affiliated with VA or DOD (Co-PI only).

c. **Duration of Proposals is a Maximum of 3 Years.** The budget must not exceed \$150,000 per year for proposals submitted by a single (VA-affiliated) PI. Collaborative proposals with a DOD Co-PI may request up to \$300,000 per year. PI or Co-PI salary may not be requested. Equipment requests are included within the funding cap. Request for up to 1 year of extended funding may be submitted to Medical Research Service during the final year of the proposed project. Extended funding will not exceed \$50,000 for a single PI, or \$100,000 for a collaborative project.

d. **Format.** Submitted proposals must conform to the format described in VA Handbook 1202.1, Medical Research Service Merit Review Award Program Handbook..

- e. **Due Date.** The deadline for proposals is July 14, 2003.

- f. **Timetable for Submission, Review, and Funding Start**

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| (1) LOIs due | March 17, 2003 |
| (2) Response to LOIs | April, 2003 |
| (3) Proposals due | July 14, 2003 |
| (4) Review of proposals | Fall, 2003 |
| (5) Earliest start date | April 1, 2004 |